

## PCT

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT



(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E SD/RS/VP41/8p	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP99/04067	International filing date (day/month/year) 28/06/1999	Priority date (day/month/year) 26/06/1998
International Patent Classification (IPC) or national classification and IPC A61K38/40		
Applicant N.V. NUTRICIA et al.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.
  - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
  - I ☒ Basis of the report
  - II ☐ Priority
  - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☒ Certain defects in the international application
  - VIII ☒ Certain observations on the international application

Date of submission of the demand  26/01/2000	Date of completion of this report  12.10.2000
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Escolar Blasco, P  Telephone No. +49 89 2399 7331  

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EXAMINATION REPORT**

International application No. PCT/EP99/04067

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-41,42-52 as originally filed

**Claims, No.:**

1-22 as originally filed

**Drawings, sheets:**

1/14-14/14 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.  
☒ claims Nos. 19, 20, 22 in respect of IA.

because:

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- ☒ the said international application, or the said claims Nos. 19, 20, 22, in respect of IA relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for the said claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	7, 10, 12-14, 17
	No:	Claims	1-6, 8, 9, 11, 15, 16, 18-22
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-22
Industrial applicability (IA)	Yes:	Claims	1-18, 21
	No:	Claims	

**2. Citations and explanations**

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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**Comments on item III**

1. Claims 19, 20 and 22 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

**Comments on item V**

1. Having regard to the prior art, the subject-matter of claims 1-6, 8, 9, 11, 15, 16 and 18-22 cannot be considered as novel (Article 33(2) PCT) for the following reasons:
  - 1.1 Antimicrobial agents comprising a polycationic peptide (lactoferrin) and a buffer are known from D1: WO 97 18827 A (see page 5, lines 23-34 and p.26, l.9-10), which discloses as well phosphate and citrate salts as buffers (see p.37, l.8-22) and a final pH value of 7.0-7.2 (see p.38, l.18-22), and thus anticipates the subject-matter of claims 1-5, 16, 18, 21 and 22.

The medicament of claim 11 is also encompassed by the disclosure of D1 (even if there is no mention of a synergy with other antibacterial, antifungal or antiviral medicaments in this document, the product claimed has been described).
  - 1.2 D1 discloses also the additional features of claims 6 (see claims 8-10), 8 (see claim 11), 9 (see p.35, l.3-6), 15, 19 (see p.35, l.9-14) and 20 (see Tables 4 and 5 in example 5).
2. The additional features contained in claims 7, 10, 12-14, 17 are considered as being trivial for the skilled man, and in any case, the application does not contain any indications that these features involve a surprising effect. Hence, they cannot be regarded as involving an inventive step (Article 33(3) PCT).
3. For the assessment of the present claims 19, 20 and 22 on the question whether

they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

### **Comments on item VII**

1. The word preventment, present in claim 1, should be substituted by prevention.

### **Comments on item VIII**

1. In claim 13 it is not clear if the medicament referred to comprises only a polycationic peptide plus an antifungal agent, or also the separately administrable medicament mentioned in claim 11; therefore claim 13 does not meet the requirements of Article 6 PCT.
2. Claim 17 is also unclear (Article 6 PCT), since it relates to the amount of peptide by referring to claim 10, which does not relate to the peptide, but to a "standard antifungal agent".
3. The term "and the like", in claims 1, 19, 21 and 22, should be deleted, since it is vague and imprecise, thereby resulting in lack of clarity (Article 6 PCT).